



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

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The Weinberg Group, Inc.  
Attention: Nicholas Fleischer, R.Ph., Ph.D.  
1220 19<sup>th</sup> Street, N.W., Suite 300  
Washington, D.C. 20036-2400

Docket No. 99P-5447/CP1

Dear Dr. Fleischer:

This is in response to your petition filed on December 20, 1999, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Cefaclor Chewable Tablets, 125 mg, 187 mg, 250 mg, and 375 mg. The listed drug products to which you refer in your petition are Ceclor® (Cefaclor) for Oral Suspension, 125 mg/5 mL, 187 mg/5 mL, 250 mg/5 mL, and 375 mg/5 mL, manufactured by Eli Lilly and Co.

Your request involves a change in dosage form from that of the listed drug products (i.e., from a for oral suspension (a powder for reconstitution) to chewable tablets). The change you request is the type of change that is authorized under the Act.

We have reviewed your petition under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act) and have determined that it is approved. This letter represents the Agency's determination that an ANDA may be submitted for the above-referenced drug products.

Under Section 505(j)(2)(C)(i) of the Act, the Agency must approve a petition seeking a dosage form which differs from the dosage form of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing dosage form.

The Agency finds that the change in dosage form for the specific proposed drug products does not pose questions of safety or effectiveness because the uses, dose, and route of administration of the proposed drug products are the same as that of the listed drug products. The Agency concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug products can be expected to have the same therapeutic effect as the listed reference drug products.

In addition, this petition was evaluated with respect to the Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients; Final Rule, published in the Federal Register (Pediatric Rule)(63 FR 66632). The agency has determined that your proposed change in dosage form is subject to the Pediatric Rule, but has concluded that investigations are not necessary to demonstrate the safety and

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effectiveness of your proposed products in the pediatric population, because the specific drug products that you reference are adequately labeled for pediatric use. Accordingly, the pediatric study requirement is waived at this time but may be reevaluated if new information is available at the time you file your applications.

The approval of this petition to allow an ANDA to be submitted for the above-referenced drug products does not mean that the Agency has determined that an ANDA will be approved for the drug products. The determination of whether an ANDA will be approved is not made until the ANDA is submitted and reviewed by the Agency.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug products will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you submit your protocol to the Office of Generic Drugs, Division of Bioequivalence for these drug products prior to the submission of your ANDAs. During the review of your application, the Agency may require the submission of additional information.

The listed drug products to which you refer in your ANDA must be the products upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,



Gary J. Buehler  
Acting Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research